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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,173	03/01/2004	Fred H. Burbank	R0367-00103	1003
7590	03/28/2006			EXAMINER TOWA, RENE T
Edward J. Lynch DUANE MORRIS LLP Spear Tower, Suite 2000 One Market San Francisco, CA 94105			ART UNIT 3736	PAPER NUMBER
DATE MAILED: 03/28/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/790,173	BURBANK ET AL.
	Examiner Rene Towa	Art Unit 3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 18 January 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1 and 40-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1 and 40-56 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 09 January 2006 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>01/03/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office action is responsive to the amendments filed January 18, 2006. Claims 1 and 40-56 are pending. No claim has been added. Claims 1, 40-41, 43, 50-51 and 54 are amended. No claim has been cancelled.

Drawings

2. The objections are withdrawn due to amendments.

Specification

3. The objections are withdrawn due to amendments.

Claim Objections

4. The objections are withdrawn due to amendments.

Claim Rejections - 35 USC § 112

5. The rejections are withdrawn due to amendments.

Claim Rejections - 35 USC § 102

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

In regards to claims 40-46, and 49-52, Essig et al. disclose an instrument assembly for isolating target tissue from an intracorporeal site, comprising:

- a. an elongate shaft 12 which has a longitudinal axis and a distal end; and
- b. an elongated electrosurgical tissue cutting element 16 which is longitudinally disposed on the elongate shaft 12 proximal of the distal end of the shaft 12, which is radially extendable from a retracted position to a radially extended position, which is capable of being rotated at least in part about the longitudinal axis in a radially extended

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arcuate position while receiving electrical power from a high frequency electrical power source 18 to electrosurgically isolate a desired tissue specimen from surrounding tissue by defining a peripheral margin about at least part of the tissue specimen (see fig. 4);

wherein the electrosurgical cutting element 16 further includes an electrical conductor configured to electrically interconnect the electrosurgical tissue cutting element 16 to high frequency electrical power source 18;

wherein the electrosurgical cutting element 16 comprises a multipolar electrode 14;

wherein the instrument assembly 10 further includes a sheath 30, which is axially movable between distal and proximal positions for selectively covering and uncovering the electrosurgical cutting element 16 (see column 4/lines 24-37);

wherein the electrosurgical cutting element 16 is configured to be manipulated to segment the tissue specimen (see column 2/lines 29-37);

wherein the electrosurgical proximal tissue cutting element 14 is configured to segment the tissue specimen after it has been isolated from the surrounding tissue (see fig. 4);

wherein the tissue cutting element 14 is configured to segment the tissue specimen as it is being retracted from said radially extended position to said radially retracted position (see fig. 4);

wherein the radially extended position comprises a first radially extended position, and wherein the electrosurgical cutting element is further actuatable to a plurality of additional radially extended positions and rotatable about the longitudinal

axis in each of said radially extended positions to selectively peripherally segment said tissue specimen (see column 4/lines 24-37).

It is noted that partial coverings of the electrosurgical cutting element 16 will result in a plurality of radially extended positions.

In regards to claims 54-56, Essig et al. disclose a system for isolating body tissue, comprising:

- a. an elongate shaft 12 having a longitudinal axis and a distal end;
- b. an electrosurgical tissue cutting element 16 disposed on the elongate shaft 12 proximal of the distal tissue cutting element 16 which is radially extendable from a radially retracted position to a radially extended position, relative to the longitudinal axis, having an arcuate shape and being movable in said radially extended position and arcuate shape to isolate a desired tissue specimen from surrounding tissue by defining a peripheral margin about said tissue specimen (see column 2/lines 29-37, 54-59); and
- c. a source 18 of radiofrequency energy which is electrically connected to the electrosurgical tissue cutting element 16;

wherein the electrosurgical tissue-cutting element comprises a multipolar electrode 14 (see fig. 1).

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,331,166.

Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 recites "a biopsy instrument for retrieving body tissue" (see line 1 of claim 1 of the patent), "a longitudinal axis" and "a distal end" (see lines 3-4 of claim 1 of the patent), "an electrosurgical tissue cutting element disposed on said distal end of the instrument" (see lines 5-9 of claim 1 of the patent).

It is clear that all the elements of claim 1 of the instant application are to be found in claim 1 of the patent. The difference between claim 1 of the instant application and claim 1 of the patent lies in the fact that the patent claim includes many more elements and is thus much more specific. Thus the invention of claim 1 of the patent is in effect a "species" of the "generic" invention of claim 1 of the instant application. It has been held that the generic invention is "anticipated" by the "species." See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claim 1 of the instant application is anticipated by claim 1 of the patent, it is not patentably distinct from claim 1 of the patent.

9. Claims 40, 44-49, and 51-54 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,699,206.

In regards to claims 40, 44-49, and 51-53, although the conflicting claims are not identical, they are not patentably distinct from each other because claim 40 recites "an instrument for isolating target tissue from intracorporeal site" (see line 1 of claim 1 of the patent), "an elongate shaft which has a longitudinal axis and a distal end" (see lines 2-3 of claim 1 of the patent), "an elongated electrosurgical tissue cutting element disposed on the elongate shaft proximal of the distal end of the shaft" (see lines 4-9 of claim 1 of the patent), "a high frequency electrical power source" (see line 17 of claim 1 of the patent).

Similarly claim 44, which is dependent on claim 40, further recites, "the electrosurgical element comprises a monopolar electrode" (see lines 1-3 of claim 9, which depends on claim 8 which depends on claim 1 of the patent).

Similarly claim 45, which is dependent on claim 40, further recites, "the electrosurgical element comprises a bipolar electrode" (see lines 1-3 of claim 10, which depends on claim 8 which depends on claim 1 of the patent).

Similarly claim 46, which is dependent on claim 40, further recites, "a sheath which is axially movable" (see claim 5, which depends on claim 1 of the patent).

Similarly claim 47, which is dependent on claim 40, further recites, "a proximal driver unit" (see line 2 of claim 6, which depends on claim 5, which depends on claim 1 of the patent).

Similarly claim 48, which is dependent on claim 47, which is dependent on claim 40, further recites, "the proximal driver unit further controls axial movement of said

shaft" (see lines 1-3 of claim 7, which depends on claim 6 which depends on claim 1 of the patent).

Similarly claim 49, which is dependent on claim 40, further recites, "electrosurgical element is configured to be manipulated to segment the tissue" (see claim 11, which depends on claim 6, which depends on claim 5, which depends on claim 1 of the patent).

Similarly claim 51, which is dependent on claim 49, which is dependent on claim 40, further recites, "the tissue cutting element is configured to segment the tissue specimen" (see claim 12, which depends on claim 11 which depends on claim 6 which depends claim 5 which depends on claim 1 of the patent).

Similarly claim 52, which is dependent on claim 51, which depends on claim 49, which is dependent on claim 40, further recites, "the radially extended position" (see claim 13, which depends on claim 12 which depends on claim 11 which depends on claim 6 which depends claim 5 which depends on claim 1 of the patent).

Similarly claim 53, which is dependent on claim 52, which depends on claim 51, which depends on claim 49, which is dependent on claim 40, further recites, "a passageway into the patient's body" (see claim 14, which depends on claim 13, which depends on claim 12 which depends on claim 11 which depends on claim 6 which depends claim 5 which depends on claim 1 of the patent).

It is clear that all the elements of claim 40 are to be found in claim 1 of the patent. The difference between claim 40 of the application and claim 1 of the patent lies in the fact that the patent claim includes many more elements and is thus much more specific.

Thus the invention of the claim 1 of the patent is in effect a "species" of the "generic" invention of claim 40. It has been held that the generic invention is "anticipated" by the "species." See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claim 40 is anticipated by claim 1 of the patent, it is not patentably distinct from claim 1. Similarly, since claims 44-49, and 51-53, are anticipated by claims 9-10, 5-7, and 11-13, respectively of the patent, claims 44-49, and 51-53 are not patentably distinct from claims 9-10, 5-7, and 11-13, respectively, of patent.

In regards to claim 54, although the conflicting claims are not identical, they are not patentably distinct from each other because claim 54 recites "a system for isolating body tissue" (see line 1 of claim 1 of the patent), "an elongate shaft which has a longitudinal axis and a distal end" (see lines 2-3 of claim 1 of the patent), "an electrosurgical tissue cutting element disposed on the elongate shaft proximal of the distal end of the shaft" (see lines 4-9 of claim 1 of the patent), "a source of radiofrequency energy" (see line 17 of claim 1 of the patent).

It is clear that all the elements of claim 54 are to be found in claim 1 of the patent. The difference between claim 54 of the application and claim 1 of the patent lies in the fact that the patent claim includes many more elements and is thus much more specific. Thus the invention of the claim 1 of the patent is in effect a "species" of the "generic" invention of claim 40. It has been held that the generic invention is "anticipated" by the "species." See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claim 54 is anticipated by claim 1 of the patent, it is not patentably distinct from claim 1.

Response to Arguments

10. Applicant's arguments filed January 18, 2005 have been fully considered but they are not persuasive. Applicant contends that Essig does not teach electrosurgically cutting or separating specimen from the surrounding tissue at a target site. This argument has been considered and has not been deemed persuasive.

In response to applicant's argument that Essig does not teach electrosurgically cutting or separating specimen from the surrounding tissue at a target site, the Applicant is reminded that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Moreover, the Essig discloses a surgical instrument 16 that is driven by an electrical power source 18 that is capable of cutting tissue as such the Examiner submits that Essig teaches an electro-surgical instrument is capable of performing the intended use as claimed above.

In view of the foregoing, the 102 rejections in view of Essig are maintained.

11. In regards to the double patenting rejections, the Applicant has submitted a Terminal disclaimer that disclaims U.S. Patent No. 6,261,241 rather than US Patent 6,331,166 as set forth in the rejections. As such, the double patenting rejections in view of US Patent No. 6,331,166 are maintained.

12. Applicant's arguments with respect to the Kieturakis rejection have been fully considered and are persuasive. Therefore, the rejections have been withdrawn.

Conclusion

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rene Towa whose telephone number is (571) 272-8758. The examiner can normally be reached on M-F, 8:00-16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RTT

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